

Docket No.: 101896-241 (DEP5293)
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:
Mark C. Boomer et al.

Application No.: 10/708,919

Filed: March 31, 2004

For: ADJUSTABLE-ANGLE SPINAL FIXATION
ELEMENT

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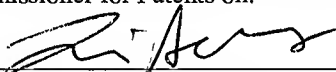
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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is DePuy Spine SARL, a Johnson & Johnson company. DePuy Spine SARL derives its rights in this application by virtue of an assignment of the application by Mark C. Boomer, Raymond F. Murphy, and Bryan S. Jones to DePuy Spine SARL, recorded at Reel 015507, Frame 0582.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1, 2, 7-10, 13-20, 42, 43, and 46-50 are currently pending in the present application, Serial Number 10/708,919. Claims 3-6, 11-12, 21-41, 44-45, and 51-59 are cancelled in the present application. Based on the Examiner's reasons for rejections of the claims, Appellants assume that claim 7 is rejected and not objected to as stated in the Office Action dated December 31, 2008. Thus, claims 1, 2, 7-10, 13-16, 20, 42, and 43 are rejected, claims 46-50 are allowed, and claims 17-19 are objected to but would be allowable if amended to include the limitations of the base claim and any intervening claims.

Accordingly, claims 1, 2, 7-10, 13-16, 20, 42, and 43 are subject to appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Office Action mailed on December 31, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention generally provides various angularly-adjustable spinal fixation devices that generally include first and second elongate members, a connecting feature formed on a terminal end of each elongate member, and a locking mechanism that is adapted to lock the first and second elongate members in a fixed positioned relative to one another. (See pg. 9, line 15 to page 10, line 1). Independent claim 1 recites a spinal fixation system, shown for example in FIG. 1A, that includes a first elongate member (e.g., 12a) having a female connector (e.g., 20a) with opposed arms (e.g., 23a, 23b) and a second elongate member (e.g., 12b) having a male connector (e.g., 20b) adapted to mate to the female connector. (See pg. 10, lines 7-18). At least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod. The first and second elongate members are coupled to

one another such that the first and second elongate members are angularly adjustable relative to one another. (See pg. 11, lines 8-21). The system further includes a mating element (e.g., 29) adapted to extend through the male and female connectors, and a fastening element (e.g., 27) adapted to mate to the male connector to cause the male connector to engage the mating element and lock the elongate members in a fixed position relative to one another. (See pg. 12, line 11 to pg. 16, line 9). Claim 1 also recites a spinal anchor that is implantable in bone and that is configured to mate to at least one of the first and second elongate members.

Independent claim 42 recites a spinal fixation system, shown for example in Figure 1A and described at pg. 10, line 7 to pg. 17, line 23, that includes first and second elongate members (e.g., 12a, 12b), each having a connecting feature (e.g., 20a, 20b) formed on a terminal end thereof. At least one of the first and second elongate members is a biocompatible, implantable-spinal fixation rod. The connecting features are coupled to one another such that the first and second elongate members are angularly adjustable relative to one another along a plane. A mating element (e.g., 29) is adapted to extend through the first and second elongate members, and a fastening element (e.g., 27) is adapted to extend into at least one of the connecting features along an axis that is substantially parallel to the plane to cause at least one of the connecting features to engage with the mating element to lock the first and second elongate members in a fixed position relative to one another. Claim 42 further requires a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members.

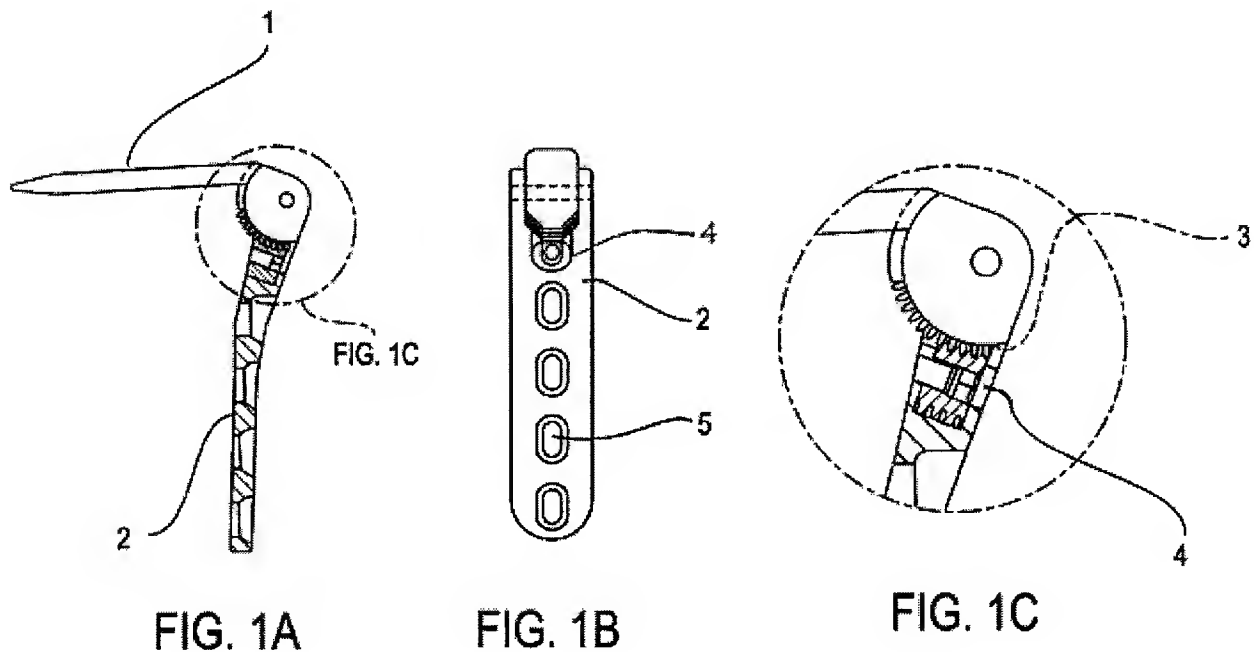
Independent claim 43 recites a spinal fixation system, shown for example in Figure 1A and described at pg. 10, line 7 to pg. 17, line 23, that includes first and second elongate members (e.g., 12a, 12b) coupled to one another such that the first and second elongate members are angularly adjustable relative to one another. The angular adjustability of each elongate member is limited to a single plane. At least one of the first and second elongate members is a biocompatible, implantable-spinal fixation rod. Claim 43 further requires a mating element (e.g., 29) adapted to extend through the first and second elongate members, and a fastening element (e.g., 27) adapted to cause at least one of the first and second elongate members to engage the mating element to lock the elongate members in a fixed position relative to one another. The fastening element extends along an axis that is substantially parallel to the single plane of angular adjustability of each elongate member. Claim 43 further recites a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A.** Whether the Examiner improperly rejects claims 1, 2, 9, 13-16, 20, 42, and 43 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue ("Yue").
- B.** Whether the Examiner improperly rejects claims 7, 8, and 10 pursuant to 35 U.S.C. §103(a) as being obvious over Yue.

VII. ARGUMENT**A. Rejection Pursuant to 35 U.S.C. 102(b) Over Yue****1. *The Scope and Content of the Prior Art***

As shown in FIGS. 1A, 1B, and 1C of Yue, which are reproduced below, Yue discloses an orthopedic plate for use in correcting problems with the long bones of the body, such as the shoulder, knee, ankle, and hip. The device of Yue includes a blade (1) that is pivotally coupled using a pivot pin to a side plate (2) having a worm gear mechanism (3) that includes an adjustment portion (4), i.e., a screw, that engages a plurality of teeth formed on a portion of the blade (1). In use, the blade (1) is inserted into bone and the plate (2) is mated to bone with screws extending through screw holes (5) formed in the plate (2). The worm gear adjustment portion (4) can be turned to manipulate the worm gear mechanism (3) and adjust the angle between the plate (2) and the blade (1).



2. The Examiner's Rejection

Claims 1, 2, 9, 13-16, 20, 42, and 43 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,007,536 of Yue ("Yue"). The Examiner argues that the blade portion (1) and the side plate (2) of Yue form the first and second elongate members recited in independent claims 1, 42, and 43. The Examiner asserts that the plate (2) includes a female connector having arms that receive a male connector, referring to FIG. 1B. The Examiner further argues that a bore (also shown in FIG. 1B) extends through the male and female connector components to allow rotation about a cylindrical mating element attached to the female connector, and that the worm gear portion (4) forms the claimed fastening element mated to the female connector. The Examiner also asserts that both the plate (2) and the blade (1) are capable of being implanted and used for spinal applications, and that the "rod and screws can be considered to be 'for' spinal fixation, since that limitation amounts to a statement of intended use, for which both are capable." December 31, 2008 Office Action, page 3.

3. Yue Does Not Teach The Claimed Invention

a. Claims 1, 2, 13-15, 20, 42, and 43

Independent claim 1 recites, in part, a fastening element adapted to mate to a male connector to cause the male connector to engage a mating element and lock the elongate members in a fixed position relative to one another. Independent claim 42 recites, in part, a fastening element adapted to extend into at least one of the connecting features to cause at least one of the connecting features to engage with the mating element to lock the first and second elongate members in a fixed position relative to one another. Independent claim 43 recites, in part, a fastening element that is adapted to cause at least one of a first and second elongate member to engage a mating element to lock the elongate members in a fixed position relative to one another. Accordingly, claims 1, 42, and 43 each generally require that the fastening element *cause* the male connector (claim 1), connecting feature (claim 42), or elongate member (claim 43) to *engage* the mating element. Yue does not teach or even suggest such a configuration.

Assuming, as the Examiner argues, that the blade portion (1) forms the second elongate member with the male connector and that the side plate (2) forms the first elongate member with the female connector (since the plate (2) includes arms that receive the blade (1)), the only component of Yue that could be considered to be the claimed mating element is the pivot pin that connects the blade portion (1) and the side plate (2). Thus, the adjustment portion (4), i.e., the adjustment screw or worm on the worm

gear, must form the claimed fastening element since it is the only part of Yue that locks the blade (1) and the plate (2). The adjustment portion (4), however, does not *cause* the male connector, i.e., the blade (1), *to engage the mating element*, i.e., the pivot pin. The worm gear adjustment portion (4) is merely used to adjust the angle between the blade portion (1) and the side plate (2). The pivot pin is never engaged by the blade (1) or the plate (2). Rather, the pivot pin is always freely rotatably disposed through the blade portion (1) and the side plate (2). Accordingly, Yue clearly fails to teach a fastening element that *causes* a male connector, connecting feature, or elongate member to engage a mating element. This alone is sufficient to render claims 1, 42, and 43 allowable over Yue.

The Examiner responds to the above argument by asserting that:

The limitations variously set forth in the claims that the fastener “cause” the connecting features to engage with the mating element, amounts to a product-by-process claim, but the resulting structure (i.e. the elongate members being locked in a fixed position and the fastener at least being part of the structure) is not different because of the product.

Appellants disagree. A product-by-process claim is “a product claim that defines the claimed product in terms of the process by which it is made.” MPEP 2173.05(p). As explained above, claims 1, 42, and 43 all require that the fastening element cause the male connector, connecting feature, or elongate member to engage the mating element. This limitation has nothing to do with the process by which the spinal fixation systems of the claims are made, but rather explains the interactions between various components of the systems. Clearly, claims 1, 42, and 43 are not product-by-process claims as suggested by the Examiner.

Appellants further note that, while the language at issue is functional in nature, this language is appropriate and must be afforded patentable weight. See, e.g., *In re Atwood*, 354 F.2d 365, 374-375 (C.C.P.A. 1966). Thus, in order for Yue to anticipate the pending claims, Yue’s device must be capable of performing the claimed function. For example, in *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356 (Fed. Cir. 1999), the claim at issue involved an in-line roller skate, and recited, in part, “a non-rigid shoe portion being permanently affixed to said base portion at least at said toe area and said heel area for substantially preventing movement therebetween at least in a horizontal plane.” The court stated that “functional language is, of course, an additional limitation of the claim” and that “functional language tells us something about the structural requirements of the attachment between the bootie and the base.”

Id. at 1363. Thus, the language involving “substantially preventing movement” was treated as a limitation of the claims. Clearly, functional limitations are to be treated as claim limitations and should be used to provide additional information about the structure of the elements of the claims. In the pending claims, the language provides information about the structural relationship between the fastening element and the male connector, connecting feature, or elongate member. As discussed above, Yue’s fastening element, i.e., the adjustment portion (4), is simply not capable of causing a male member, connecting feature, or elongate member, i.e., the blade (1), to engage the mating element, i.e., the pivot pin. The adjustment portion has no effect on the mating relationship between the blade and the pivot pin. Accordingly, because Yue’s adjustment portion is not capable of performing the recited function, Yue simply cannot anticipate the claimed invention.

Independent claims 1, 42, and 43 therefore distinguish over Yue and represent allowable subject matter. Claims 2, 13-15, and 20 are allowable at least because they depend from claim 1.

b. Claim 9

Claim 9 recites that the first elongate member is a biocompatible, implantable spinal fixation rod and the second elongate member is a spinal fixation plate. Yue simply cannot anticipate claim 9 because Yue is lacking both the claimed spinal fixation rod and the claimed spinal fixation plate.

With regard to the first component, i.e., the spinal fixation rod, Yue discloses a *plate* (2). This is the only component of Yue that can be considered to form the claimed first component because this is the only component that has a female connector, as required by claim 1. For obvious reasons, Yue’s *plate* cannot be considered to be a spinal fixation *rod*.

With regard to the second component, i.e., the spinal fixation plate, Yue discloses a *blade* (1). The blade is the only component of Yue that can be considered to form the claimed second component because this is the only component that has a male connector, as required by claim 1. While the blade (1) of Yue can be considered to be a plate, since the blade is flat as explained at col. 3, lines 12-15, the blade certainly cannot be considered to be a “spinal fixation plate” as this term is generally understood by a person having ordinary skill in the art. Spinal fixation plates are configured to be used in the spine and attach to one or more vertebrae. Yue’s blade is configured to be used in the hip, knee, ankle, and shoulder. See col. 2, line 67 to col. 3, line 1. As such, the size of the blade would prevent the blade

from being used as a spinal fixation plate, and no person having ordinary skill in the art would ever consider Yue's blade to be a spinal fixation plate.

Accordingly, dependent claim 9 distinguishes over Yue and represents allowable subject matter.

c. Claim 16

Claim 16 recites that the cylindrical member, a part of the mating element, is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member. As explained above, the pivot pin is the only component that can be considered to form the claimed mating element. Yue does not teach that the pivot pin is fixedly coupled a portion of either the blade (1) or the plate (2). Rather, the pivot pin is freely rotatably disposed through both the blade (1) and the plate (2). Accordingly, dependent claim 16 distinguishes over Yue and represents allowable subject matter.

B. Rejection Pursuant to 35 U.S.C. 103(a) Over Yue

1. The Examiner's Rejection

Claims 7¹, 8, and 10 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,007,536 of Yue. Regarding claim 7, the Examiner asserts that Yue discloses the claimed invention except for the device being comprised of rods (or plates) instead of one rod and one plate.² The Examiner argues that "given the disclosure of both a rod and a plate, it would have been obvious to a person of ordinary skill in the art, to have configured the device with two rods (or plates) instead of one rod and one plate, in order to address the exigencies of surgical necessity of patient anatomy." December 31, 2008 Office Action, page 4. The Examiner did not address claim 8. Regarding claim 10, the Examiner asserts that Yue discloses the claimed invention except for explicitly disclosing different diameters for the elongate members. The Examiner argues that it would have been obvious to form the device from different diameters "since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art." December 31, 2008 Office Action, page 4.

¹ The Examiner rejects claim 8 in the December 31, 2008 Office Action, however the Examiner's arguments are directed to the language of claim 7. Accordingly, Appellants assume the Examiner intended to reject claim 7 in addition to claim 8.

² Appellants note that claim 7 requires that the first and second elongate members are rods, not plates.

2. The Claimed Invention Distinguishes Over Yue

a. Claim 7

Claim 7 recites that the first and second elongate members are each spinal fixation rods. At the outset, Appellants note that claim 7 depends from claim 1, and thus distinguishes over Yue for all of the reasons discussed above with respect to claim 1. Claim 7 further distinguishes over Yue because Yue only teaches two *plates*, the blade (1)³ and the plate (2). Neither the blade (1) nor the plate (2) can be considered to be a rod, much less a spinal fixation rod, as both the blade (1) and the plate (2) are sized and shaped to be used with the long bones of the body and could not be used in the spine as a spinal fixation rod. In addition, Yue cannot be modified as suggested by the Examiner because such a modification is specifically contrary to the teachings of Yue. No person having ordinary skill in the art would modify the side plate (2) and the blade (1) of Yue to each be a spinal fixation rod. The blade (1) is specifically “fashioned to gain fixation in cancellous or spongy bone by virtue of its flat shape and slightly curved edges.” Col. 3, lines 13-15. Any modification to the blade would thus hinder its ability to function as required by Yue. Likewise, Yue’s side plate (2) cannot be replaced with a spinal fixation rod because the side plate (2) has a configuration that requires a flat shape. In particular, as explained at col. 3, lines 25-29, the side plate (2) is placed against and rests flush with an outer surface of the bone. A spinal fixation rod would be difficult to place flush against bone, and moreover could not be easily screwed onto the bone.

Accordingly, the modification proposed by the Examiner is not obvious, and therefore claim 7 further distinguishes over Yue and represents allowable subject matter.

b. Claim 8

Claim 8 recites that the first elongate member is a spinal fixation plate and the second elongate member is a spinal fixation rod. At the outset, Appellants note that claim 8 depends from claim 1, and thus distinguishes over Yue for all of the reasons discussed above with respect to claim 1. As explained above, Yue only teaches two plates, the blade (1) and the plate (2). In particular, the plate (2), which is the only component of Yue that can be considered to form the claimed first elongate member, cannot be considered to be a “spinal fixation plate” for the same reasons discussed with respect to claim 9. The blade (1), which is the only component of Yue that can be considered to form the claimed second elongate member, cannot be considered to be a “spinal fixation rod” for the same reasons discussed

³ Yue specification states at col. 3, lines 12-15, that the blade is flat, indicating that the blade is a plate.

above with respect to claim 7. Accordingly, claim 8 further distinguishes over Yue and represents allowable subject matter.

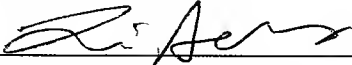
c. Claim 10

Claim 10 recites that the first elongate member has a diameter different than a diameter of the second elongate member. At the outset, Appellants note that claim 10 depends from claim 1, and thus distinguishes over Yue for all of the reasons discussed above with respect to claim 1. Claim 10 further distinguishes over Yue because Yue simply has no teaching regarding the diameters of the plate and blade, and thus there is no motivation to make the modification suggested by the Examiner. Yue's blade portion (1) is "fashioned to gain fixation in cancellous or spongy bone by virtue of its flat shape and slightly curved edges" (*see* Col. 3, lines 12-15 of Yue), and the plate (2) is sized and shaped to be flush to bone. Thus, Yue specifically forms the blade portion (1) and the side plate (2) with a certain shape to be utilized to provide fixation for long bones of the body, and a person of ordinary skill in the art would not modify the diameters of the blade (1) and the plate (2) as required by claim 10. Thus, claim 10 further distinguishes over Yue and represents allowable subject matter.

VIII. CONCLUSION

For the reasons noted above, Appellants submit that the pending claims define patentable subject matter. Accordingly, Appellants request that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Respectfully submitted,



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IX. APPENDIX A: CLAIMS ON APPEAL

1. (Previously Presented) A spinal fixation system, comprising:
 - a first elongate member having a female connector with opposed arms and a second elongate member having a male connector adapted to mate to the female connector, the first and second elongate members coupled to one another such that the first and second elongate members are angularly adjustable relative to one another;
 - a mating element adapted to extend through the male and female connectors;
 - a fastening element adapted to mate to the male connector to cause the male connector to engage the mating element and lock the elongate members in a fixed position relative to one another; and
 - a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.
2. (Previously Presented) The spinal fixation system of claim 1, wherein angular adjustment of each elongate member is limited to a single plane.
- 3-6. (Cancelled).
7. (Previously Presented) The spinal fixation system of claim 1, wherein the first and second elongate members each comprise a biocompatible, implantable spinal fixation rod.
8. (Previously Presented) The spinal fixation system of claim 1, wherein the first elongate member is a spinal fixation plate and the second elongate member is a biocompatible, implantable spinal fixation rod.
9. (Previously Presented) The spinal fixation system of claim 1, wherein the first elongate member is a biocompatible, implantable spinal fixation rod and second elongate member is a spinal fixation plate.
10. (Previously Presented) The spinal fixation system of claim 1, wherein the first elongate member has a diameter that is different than a diameter of the second elongate member.

11-12. (Cancelled).

13. (Previously Presented) The spinal fixation system of claim 1, wherein the opposed arms define a recess therebetween for receiving the male connector.

14. (Previously Presented) The spinal fixation system of claim 1, further comprising a bore extending through the opposed arms on the female connector and through the male connector, and the mating element extending through the bore for mating the male and female connectors to one another.

15. (Previously Presented) The spinal fixation system of claim 14, wherein the mating element comprises a cylindrical member, the cylindrical member being adapted to allow at least one of the first and second elongate members to rotate thereabout.

16. (Previously Presented) The spinal fixation system of claim 15, wherein the cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member.

17. (Objected To) The spinal fixation system of claim 16, wherein the fastening element is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector.

18. (Objected To) The spinal fixation system of claim 17, wherein the fastening element comprises a slot extending through the male connector such that the male connector is in the form of a clamp, and wherein the fastening element is adapted to engage the male connector to clamp the cylindrical member within the bore.

19. (Objected To) The spinal fixation system of claim 18, wherein the fastening element comprises a threaded member.

20. (Previously Presented) The spinal fixation system of claim 1, wherein the female connector and male connector of the first and second elongate members rotate about a central axis extending substantially perpendicular to an axis of each first and second elongate members.

21-41. (Canceled).

42. (Previously Presented) A spinal fixation system, comprising:

first and second elongate members, each having a connecting feature formed on a terminal end thereof, the connecting features being coupled to one another such that the first and second elongate members are angularly adjustable relative to one another along a plane;

a mating element adapted to extend through the first and second elongate members;

a fastening element adapted to extend into at least one of the connecting features along an axis that is substantially parallel to the plane to cause at least one of the connecting features to engage with the mating element to lock the first and second elongate members in a fixed position relative to one another; and

a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.

43. (Previously Presented) A spinal fixation system, comprising:

first and second elongate members coupled to one another such that the first and second elongate members are angularly adjustable relative to one another, the angular adjustability of each elongate member being limited to a single plane;

a mating element adapted to extend through the first and second elongate members;

a fastening element adapted to cause at least one of the first and second elongate members to engage the mating element to lock the elongate members in a fixed position relative to one another, the fastening element extending along an axis that is substantially parallel to the single plane of angular adjustability of each elongate member; and

a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.

44-45. (Cancelled).

46. (Allowed) A spinal fixation system, comprising:

a first elongate element having a clamping mechanism formed on a terminal end thereof;

a second elongate element having a terminal end adapted to be received by the clamping mechanism on the first elongate element;

a fastening element adapted to engage and close the clamping mechanism such that the second elongate member can be maintained in a fixed position relative to the first elongate member; and

a spinal anchor implantable in bone and configured to mate to at least one of the first and second elongate members;

wherein at least one of the first and second elongate members is a biocompatible, implantable spinal fixation rod.

47. (Allowed) The spinal fixation system of claim 46, wherein the first elongate element has a diameter different from a diameter of the second elongate element.

48. (Allowed) The spinal fixation system of claim 46, wherein the first elongate element has a diameter that is the same as a diameter of the second elongate element.

49. (Allowed) The spinal fixation system of claim 46, wherein the terminal end of the second elongate element is positioned at an angle relative to a longitudinal axis of the second elongate element.

50. (Allowed) The spinal fixation system of claim 49, wherein the angle is about 90°.

51-59. (Cancelled).

X. APPENDIX B: EVIDENCE

No evidence submitted.

XI. APPENDIX C: RELATED PROCEEDINGS

No related proceedings.

1815338.1